

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0504147	<b>(X3) Date Survey Completed</b> 03/21/2019
<b>Name of Provider or Supplier</b> Memorial Hospital	<b>Street Address, City, State</b> 1110 Sarah Dewitt Drive, Gonzales, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A survey for recertification was performed March 19-20, 2019. The laboratory was in compliance with the CLIA regulations and recertification is recommended. Based on review of laboratory records, the laboratory had not performed any tests for histopathology since the previous survey cycle and therefore, the speciality of histopathology could not be certified. The CMS-116 will be updated to remove the speciality of histopathology.
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for storage of laboratory reagents. The findings were: 1. Surveyor observation made in the microbiology section on March 19, 2019 at 11:00 hours revealed the laboratory's fungal stain reagent, Chlorazol Black E, (lot number K19142) was stored on the bench top by the sink. 2. Review of the manufacturer's instructions located on the label of the container stated, "Store in a dark place." 3. Interview with testing personnel six (as listed on Form CMS-116) on March 19, 2019 at 11:05 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the temperature of the environment where laboratory supplies were located. The findings were: 1. Surveyor observation made on March 20, 2019 at 16:00 hours at the Nurse's Station revealed no means to monitor the temperature of the environment. 2. Review of supplies located at the Nurse's Station revealed the following items: Modified Amies Swabs Lot 7J18A 6 swabs Copan Transport System Lot 180015000 2 swabs 3. Review of the manufacturer's instructions for Modified Amies Swabs located on package labeling revealed the items were to be stored at, "4-25 degrees Celsius or 40-77 degrees Fahrenheit." 4. Review of the manufacturer's instructions for Copan Transport System located on package labeling revealed the items were to be stored at, "5-25 degrees Celsius." 5. Interview with the technical consultant on March 20, 2019 at 16:03 hours at the Nurse's Station confirmed the findings.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure laboratory reagents were labeled with contents and expiration dates. The findings were: 1. Surveyor observation made in the laboratory on March 19, 2019 at 09:50 hours revealed a bottle of reagent not labeled with the identification of the contents or the expiration date. 2. Surveyor observation made in the microbiology section on March 20, 2019 at 11:08 hours revealed a bottle of reagent not labeled with the identification of the contents or the expiration date. 3. Interview with the technical consultant on March 20, 2019 at 11:30 hours confirmed the findings.

**D5545**

**HEMATOLOGY**  
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on surveyor observation, review of laboratory MNPT records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to enter the geometric mean into the Instrumentation Laboratory ACL TOP 350 coagulation analyzer. The findings were: 1. Surveyor observation made on March 20, 2019 at 08:00 hours in the laboratory revealed the geometric mean entered into the ACL TOP 350 was 10.3. 2. Review of the current lot number for MNPT records revealed RecombiPlastin 2G reagent was approved for use on December 19, 2018. The lot number for the RecombiPlastin 2G reagent was N0588147 with an expiration date of May 31, 2020. 3. Review of the calculations for the current MNPT studies revealed the actual geometric mean was 10.6. The incorrect geometric mean was entered into the ACL TOP 350 analyzer. 4. Review of patient results from January 1, 2019 to March 20, 2019 revealed the following patients were performed with the incorrect geometric mean was used (see patient alias list). 5. Interview with the technical consultant on March 20, 2019 at 09:00 hours in the laboratory confirmed the findings. After he recalculated the geometric mean, he agreed that the actual geometric mean was 10.6 not 10.3. Key: MNPT - mean normal prothrombin time

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of facility and laboratory policies, review of Patient Care Committee Minutes, review of patient records, review of physician progress notes, and confirmed in interview with facility personnel, the laboratory's quality assessment (QA) system failed to include a review of the effectiveness of procedures to prevent potentially missed transfusion reactions. The findings were: 1. Review of facility policy titled, "Transfusion of Filtered Red Blood Cells" approved by the laboratory director on January 9, 2019, it stated: "6. Take the vital signs including blood pressure and record on blood request slip." "13. Adverse reactions include chilling, backache, headache, nausea or vomiting, tachycardia, tachypnea, respiratory distress, skin rash, itching, hypotension, or increase in temperature by 1.8 degrees Fahrenheit." "14. Take and record vital signs with the blood pressure at 5 minutes, 15 minutes, and then every 30 minutes during the entire transfusion using blood transfusion record." "23. For symptoms that occur during transfusion, stop transfusion and notify physician of a suspected transfusion reaction. Obtain orders to either continue or discontinue the blood transfusion." 2. Review of laboratory policy titled, "Transfusion Reaction Procedure" approved by the laboratory director on January 10, 2017, stated: "PURPOSE: This policy will outline the steps that need to be taken in the event that there is an suspected transfusion reaction. PROCEDURE: In the event of a suspected transfusion reaction the nursing personnel attending the patient shall notify the responsible physician. If the physician stops the transfusion based on calling it a possible transfusion reaction or if the reaction involves a rise in the patient's temperature of 1.8 degrees Fahrenheit or greater, the patient has discomfort/flank pain, and the patient had a normal temperature before the transfusion the following

protocol must be followed. -The Registered Nurse shall stop the transfusion and notify the physician and the blood bank personnel. -The Registered Nurse will complete the patient information portion of the transfusion reaction form and return it to the lab. -The Registered Nurse will collect a post reaction urine specimen and send to the lab. -The Laboratory will collect a new properly labeled blood sample (avoiding hemolysis) from the patient. The Laboratory will perform the "Partial Transfusion Reaction" work-up: -The label on the blood containers, pre and post reaction sample tubes, requisition, and log sheets will be checked to detect whether there has been a clerical error made in identifying the patient or the blood. -The patient's post-reaction serum shall be inspected for evidence of hemolysis and icterus using a pre-reaction sample for comparison if available. -A Type and Rh will be performed on a post reaction sample. -A DAT will be performed on the patient's pre and post reaction transfusion specimen using the polyvalent AHG anti-sera. -The results of the above mentioned procedures shall be documented in the appropriate spaces on the "Transfusion Reaction Form" with the technologist/technician performing the work-up signing, dating, and timing the form. -If hemolysis or a positive DAT is noted then the Extended Transfusion Reactions Investigation must be completed. ..."

Definition of possible adverse blood transfusion reactions: -Acute Hemolytic Transfusion Reaction: Symptoms -Chills, fever, rigors, pain in the abdomen, chest, flank, or lower back, flushing of the face, hemoglobinuria, tachycardia, shock, tachypnea, hypotension, dyspnea, DIC, acute renal failure -Allergic Transfusion Reaction: Symptoms Urticaria, flushing, pruritus, chills, nausea, vomiting, wheezing, brochospasm, dyspnea, fever, anxiety, hypotension, cyanosis - Febrile Transfusion Reaction Symptoms Fever, chills, flushing, back pain, malaise, tachycardia, confusion, nausea, vomiting, headache -Transfusion Related Acute Lung Injury (TRALI) Symptoms Fever, chills, dyspnea, hypotension, new onset bilateral pulmonary edema, hypertension followed by hypotension, cyanosis -Transfusion Associated Circulatory Overload (TACO) Symptoms 1 to 2 hours post transfusion-gallop, jugular venous distension, elevated central venous pressure, dyspnea, hypertension, cyanosis, cardiogenic pulmonary edema

3. Review of Patient Encounter 01318193 A. Review of the "Patient Care Committee Minutes" from February 27, 2018 under, "Blood Usage Review" it stated, "...There was one case referred for committee review. In this case, the patient's temperature rose 4.2 degrees from the time the unit was started but the unit was not stopped as required by policy and no investigation was performed at that time. After this was discovered during preparations for this meeting, a review was performed. It was determined the patient's rise in temperature was not related to the transfusion. The staff member caring for the patient during this transfusion has been educated on the policy and what she should have done at the time..." B. Review of chart record for patient encounter 01318193 revealed the patient was transfused with 2 units of filtered packed red blood cells on January 3, 2018. The second unit was documented as starting at 16:20 hours. The following patient temperatures were documented during the course of the transfusion: 20:05 hours 98.4 degrees Fahrenheit (Notes: "No symptom of reaction) 20:35 hours 101.4 degrees Fahrenheit (Notes: "No symptom of reaction) 21:05 hours 102.6 degrees Fahrenheit (Notes: "No symptom of reaction) 21:30 hours 101.6 degrees Fahrenheit (Notes: "No symptom of reaction) Further documentation on the patient's Blood Transfusion Record revealed "Tylenol given at 21:18 and that the transfusion was completed at 21:30 hours." C. The patient's change in temperature met the facility's and laboratory's defined criteria for a potential transfusion reaction workup. There was no documentation that the unit was stopped or that the physician was notified as to a suspected transfusion reaction so that he or she could provide the order to either continue or discontinue the blood transfusion. D. In an interview with the technical consultant on March 21, 2019 at 11:00 hours in his office confirmed the findings. He revealed that he was unaware of this

patient case and went on to say that he was not a member of the Blood Utilization Committee. He further revealed that the laboratory does not regularly see a patient's Blood Transfusion Record. E. The laboratory's QA program did not identify and correct problems in its post analytic systems. 4. Review of patient encounter 01299645 A. Review of the "Patient Care Committee Minutes" from August 30, 2017 under, "Blood Usage Review" stated, "...There was one case referred for committee review due to physician documentation the patient had a transfusion reaction. This was not worked up as such because the nursing staff did not inform the Laboratory of a possible reaction. Further investigation and discussion of the case revealed that a reaction did not occur and the physician agreed to amend his documentation to show the patient did not have a transfusion reaction..." B. Review of chart record for patient encounter 01299645 revealed the patient was transfused with 2 units of filtered packed red blood cells on July 28, 2017. At 19:55 hours in the nurse's notes the following documentation was noted, "Rash on right side cheek, stopped transfusion." C. Review of the physician's notes it stated, "2. Blood transfusion reaction. As mentioned, nearing the end of her 1st blood transfusion, the patient first complained of some nausea which was alleviated with IV Phenergan, and the patient developed generalized urticarial rash which got a little better with Benadryl and then the patient developed atypical chest pain, shortness of breath, and symptoms resolved fairly soon after discontinuation of the blood transfusion. She received approximately 90% of that 1st unit. Through the evening, the patient slept well and had no further complication, and on hospital day 2, the patient tolerated her 2nd transfusion without incident." and; "3. Chest pain. Most likely secondary to her blood transfusion. The patient's symptoms warranted a cardiac workup. The EKG at the time of her chest pain simply showed sinus tachycardia and without a strain pattern, and serial cardiac enzymes were negative. No further workup is anticipated." D. Because the transfusion reaction workup was not performed according to policy, the laboratory did not perform a transfusion workup until August 9, 2017 (12 days after the patient's transfusion). E. On August 9, 2017, the laboratory director stated, "Nursing did not initiate the reaction protocol correctly. The protocol was started once the doctor's dictation was reviewed and he had referenced a transfusion reaction. The issue is going before the patient care committee." F. In interview with the medical records manager on March 21, 2019 at 10:00 hours in the technical consultant's office she confirmed that it was her understanding that the physician's notes would be amended and that the patient did not have a true transfusion reaction, but when she went back to review the notes on March 21, 2019 for this survey, it was discovered that the physician notes in fact had not been amended and still reflected that the patient had a transfusion reaction.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of facility and laboratory policies, review of patient records, review of Patient Care Committee Minutes, review of transfusion records, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory's quality assurance (QA) program identified and corrected problems in its analytic systems. (refer to D5793)